One Step
Morphine Test Device (Urine)
Package Insert

(Catalog Number: 1188-C)

BIOMERICA

A rapid, one step test for the qualitative detection of Morphine, Opiates, and Heroin in human urine.

For professional in vitro diagnostic use only.

INTENDED USE

The One Step Morphine Test Device (Urine) is a lateral flow chromatographic immunoassay for the detection of morphine, opiates, and heroin in urine.

SUMMARY

Opioid analgesics comprise a large group of substance which control pain by depressing the central nervous system. Large dose of morphine can produce higher tolerance level and physiological dependency in users, and may lead to substance abuse. Morphine is excreted unmetabolized, and is also the major metabolic product of codeine and heroin. Morphine is detectable in the urine for several days after an opiate dose (1).

The One Step Morphine Test Device (Urine) is a rapid urine screening test that can be performed without the use of an instrument. The test utilizes a monoclonal antibody to selectively detect elevated levels of morphine in urine. The One Step Morphine Test Device (Urine) yields a positive result when the morphine in urine reaches 300 ng/mL. This is the suggested screening cut-off for positive specimens set by the Substance Abuse and Mental Health Services Administration (SAMHSA, USA).

PRINCIPLE

The One Step Morphine Test Device (Urine) is an immunoassay based on the principle of competitive binding. Drugs which may be present in the urine specimen compete against the drug conjugate for binding sites on the antibody.

During testing, a urine specimen migrates upward by capillary action. Morphine, if present in the urine specimen below 300 ng/mL, will not saturate the binding sites of the antibody coated particles in the test device. The antibody coated particles will then be captured by immobilized morphine conjugate and a visible colored line will show up in the test line region. The colored line will not form in the test line region if the morphine level is at or above 300 ng/mL because it will saturate all the binding sites of anti-morphine antibodies.

A drug-positive urine specimen will not generate a colored line in the test line region because of drug competition, while a drug-negative urine specimen will generate a line in the test line region because of the absence of drug competition.

To serve as a procedural control, a colored line will always appear at the control line region if the test has been performed properly.

REAGENTS

The test device contains anti-morphine particles and morphine conjugate coated on the membrane.

PRECAUTIONS

- For professional *in vitro* diagnostic use only. Do not use after the expiration date.
- The test device should remain in the sealed pouch until use.
- All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
- The test device should be discarded in a proper biohazard container after testing.

STORAGE AND STABILITY

Store as packaged in the sealed pouch at 4-30°C. The test device is stable through the expiration date printed on the sealed pouch. The test device must remain in the sealed pouch until use. **DO NOT FREEZE.** Do not use beyond the expiration date.

SPECIMEN COLLECTION AND PREPARATION

Urine Assay

The urine specimen must be collected in a clean and dry container. Urine collected at any time of the day may be used. Urine specimens exhibiting visible precipitates should be centrifuged, filtered, or allowed to settle to obtain a clear supernatant for testing.

Specimen Storage

Urine specimens may be stored at 2-8°C for up to 48 hours prior to testing. For prolonged storage, specimens may be frozen and stored below -20°C. Frozen specimens should be thawed and mixed before testing.

PROCEDURE

Materials Provided

- Test devices
- Disposable droppers
- Package insert

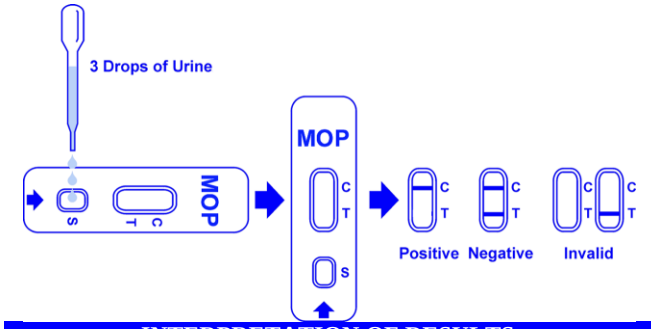
Materials Required But Not Provided

- Specimen collection container
- Timer

DIRECTIONS FOR USE

Allow the test strip, urine specimen and/or controls to equilibrate to room temperature (15-30°C) prior to testing.

1. Bring the pouch to room temperature before opening it. Remove the test device from the sealed pouch and use it as soon as possible.
2. Place the test device on a clean and level surface. Hold the dropper vertically and transfer 3 full drops of urine (approx. 100µl) to the specimen well (S) of the test device, and then start the timer. Avoid trapping air bubbles in the specimen well (S). See the illustration below.
3. Wait for the red line(s) to appear. The result should be read at 5 minutes. It is important that the background is clear before the result is read. Do not interpret the result after 10 minutes.



INTERPRETATION OF RESULTS

(Please refer to illustration above)

POSITIVE: One red line appears in the control region (C). No line appears in the test region (T). This positive result indicates that the morphine concentration is at or above the detectable level (300 ng/mL).

NEGATIVE:* Two lines appear. One red line should be in the control region (C), and another apparent red or pink line should be in the test region (T). This negative result indicates that the morphine concentration is below the detectable level (300 ng/mL).

INVALID: **Control line fails to appear.** Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test device. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

*** NOTE**: The shade of red in the test region (T) may vary, but it should be considered negative whenever there is even a faint pink line.

QUALITY CONTROL

A procedural control is included in the test. A red line appearing in the control region (C) is the internal procedural control. It confirms sufficient specimen volume and correct procedural technique. A clear background is required.

Control standards are not supplied with this kit; however it is recommended that positive and negative controls be tested as good laboratory testing practice to confirm the test procedure and to verify proper test performance.

LIMITATIONS

1. The One Step Morphine Test Device (Urine) provides only a preliminary analytical result. A secondary analytical method must be used to obtain a confirmed result. Gas

chromatography and mass spectrometry (GC/MS) are the preferred confirmatory methods (2).

2. The MOP One Step Morphine Test Device (Urine) is a qualitative screening assay and can not determine either the drug concentration in the urine or the level of intoxication.
3. It is possible that technical or procedural errors, as well as other interfering substances in the urine specimen may cause erroneous results.
4. Adulterants, such as bleach and/or alum, in urine specimens may produce erroneous results regardless of the analytical method used. If adulteration is suspected, the test should be repeated with another urine specimen.
5. Certain medications containing opiates or opiate derivatives may produce a positive result. Additionally, foods and tea containing poppy products may also produce a positive result.

PERFORMANCE CHARACTERISTICS

Sensitivity

The Substance Abuse and Mental Health Services Administration (SAMHSA) has set the screening cut-off for positive specimens at 300 ng/mL for morphine (3). The One Step Morphine Test Device (Urine) has been shown to detect 300 ng/mL of morphine in urine at 5 minutes.

Specificity

The following table lists compounds that are positively detected in urine by the One Step Morphine Test Device (Urine) at 5 minutes.

Table 1.

Compound	Concentration (ng/mL)
Codeine	300
Glucuronide	300
Hydrocodone	500
Hydromorphone	600
Levophanol	5,000
Meperidine	80,000
Morphine	300
Morphine 3-β-D-glucuronide	500
Nalorphine	1,000
Naloxane	100,000
Norcodeine	60,000
Oxycodone	20,000
Oxymorphone	60,000
Procaine	100,000
Thebaine	5,000

Cross-Reactivity

A study was conducted to determine the cross-reactivity of the test with compounds in urine not associated with morphine. The following compounds show no cross-reactivity when tested with the One Step Morphine Test Device (Urine) at a concentration of 100 µg/mL (Table 2).

Table 2. **Non Cross-Reacting Compounds**

4-Acetamidophenol	Diflunisal	Oxazepam
Acetophenetidin	Digoxin	Oxolinic acid
N-Acetylprocainamide	Diphenhydramine	Oxymetazoline
Acetylsalicylic acid	Doxylamine	p-Hydroxymeth-
Aminopyrine	Ecgonine	amphetamine
Amitryptyline	Ecgonine methylester	Papaverine
Amobarbital	(+) Ephedrine	Penicillin-G
Amoxapine	(±) Ephedrine	Pentazocaine
Amoxicillin	(-) Ephedrine	Pentobarbital
D,L-Amphetamine	(-) Ψ Ephedrine	Perphenazine
L-Amphetamine	Erythromycin	Phencyclidine
Apomorphine	β-Estradiol	Phendimetrazine
Aspartame	Estrone-3-sulfate	Phenelzine
Atropine	Ethyl-p-aminobenzoate	Phenobarbital
Benzilic acid	Fenoprofen	Phentermine
Benzoic acid	Furoxmide	Phentoin
Benzoylecgonine	Gentisic acid	L-Phenylethlamine
Benzphetamine	Hydralazine	β-Phenyllethylamine
Butabarbital	Hydrochlorothiazide	Phenylpropanolamine
Cannabidiol	Hydrocortisone	
Chloralhydrate	O-Hydroxyhippuric acid	
Chloramphenicol	β-Hydroxytyramine	
Chlordiazepoxide	Ibuprofen	
Chlorothiazide	Imipramine	
Chlorpromazine	Iproniazid	
Chlorquine	(-) Isoproterenol	
Cholesterol	Isoxsuprine	
Clomipramine	Ketamine	
Clonidine	Ketoprofen	
Cocaine	Labetalol	
Cortisone	Lidoccaine	
(-) Cotinine	Loperamide	
Creatinine	Loxapine succinate	
Deoxycorticosterone	Maprotiline	
Dextromethorphan	Meprobamate	
Diazepam	Methadone	
Diclofenac	Methaqualone	
Diethylpropion	Methoxyphenamine	
(+) 3,4-Methylenedioxy-	Prednisolone	
amphetamine	Prednisone	
(+) 3,4-Methylenedioxy-	Promazine	
methamphetamine	Promethazine	
Methylphenidat	D,L-Propanolol	
Methyprylon	Propiomazine	
Nalidixic acid	D-Propoxyphene	
Naltrexone	D-Pseudoephedrine	
Naproxen	Quinidine	
Niacinamide	Quinine	
Nifedipine	Rantidine	
Norethindrone	Salicylic acid	
Noroxymorphone	Secobarbital	
D-Norpropoxyphene	Serotonin	
(-) Norpseudoephedrine	Sulfamethazine	
Noscapine	Sulindac	
Nylidrin	Temazepam	
D,L-Octopamine	Tetracycline	
Oxalic acid	Δ⁸ -THC	
Oxazepam	Δ⁹-THC	
Oxolinic acid	11-nor-Δ⁹ -THC-9-COOH	
Oxymetazoline	Tetrahydrocortisone	
p-Hydroxymeth-	Tetrahydrozoline	
amphetamine	Thiamine	
Papaverine	Thioridazine	
Penicillin-G	D,L-Thyroxine	
Pentazocaine	Tolbutamide	
Pentobarbital	Triaamterene	
Perphenazine	Trifluoperazine	
Phencyclidine	Trimethoprim	
Phendimetrazine	Trimipramine	
Phenelzine	Tryptamine	
Phenobarbital	D,L-Tryptophan	
Phentermine	Tyramine	
Phentoin	D,L-Tyrosine	
L-Phenylethlamine	Uric acid	
β-Phenyllethylamine	Verapamil	
Phenylpropanolamine	Zomepirac	

BIBLIOGRAPHY

1. Tietz NW. *Textbook of Clinical Chemistry.* W.B. Saunders Company. 1986; 1735
2. Baselt RC. Disposition of Toxic Drugs and Chemicals in Man. 2nd Ed. Biomedical Publ., Davis, CA. 1982; 488
3. Hawks RL, CN Chiang. *Urine Testing for Drugs of Abuse*. National Institute for Drug Abuse (NIDA), Research Monograph 73, 1986

	Storage Temperature	EC REP	Authorized Representative
LOT	Lot Code		Caution, See Instructions
	Expiration	IVD	For in vitro diagnostic use
	Manufacturer	REF	Catalog No.

Biomerica, Inc.,17571 Von Karman Avenue
Irvine, CA 92614 USA

EC REP

according to IVDD 98/79/ EC
MDSS
Burckhardtstrasse 1
30163 Hannover, Germany

1188-C.doc MAR2005